UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,119	03/16/2005	Jan Baker	0123.1005-PCT-US	8922

20311 7590 03/19/2008

LUCAS & MERCANTI, LLP
475 PARK AVENUE SOUTH
15TH FLOOR
NEW YORK, NY 10016

EXAMINER	
HOBBS, MICHAEL L	

ART UNIT	PAPER NUMBER
4151	

MAIL DATE	DELIVERY MODE
03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,119	BAKER, JAN	
	Examiner	Art Unit	
	MICHAEL L. HOBBS	4151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03/16/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03/16/2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/16/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 6 contains the trademark/trade name VIASPAN™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the preservative solution commonly known in the art as University of Wisconsin solution and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 6, 7, 9, 11, 12, 14, 15, 16, 19, 20, 22, 23, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hassanein (U.S. 6,100,082).

6. For claim 1, Hassanein teaches a cover that is fitted on top of the perfusion system (col. 11 lines 46-48, Fig. 4 element 180) that provides additional protection to the system. Also, Hassanein teaches a organ container (col. 11 lines 20-21, Fig. 4 element 20) that allows for the return of any blood that escapes the organ (col. 4 lines 40-41) that includes a cover assembly that has a clamping ring which has two-halves, i.e. the ring opens in a horizontal motion, that are connected by a hinge (col. 7 lines 36-38, Fig. 3 element 22). Also, Hassanein includes an oxygen bottle with regulator for providing the right percentage of oxygen and carbon dioxide to the heart organ (col. 11 lines 32-33, Fig. 4 element 178) and is introduced to the blood perfusion via the oxygenating membrane. The blood perfusion is returned to the reservoir via a drain connector in the organ container (col. 4 lines 37-39, Fig. 1 elements 24-26,30) and the blood perfusion is returned to the reservoir by the pulmonary artery return line (col. 7 lines 9-10, Fig. 1 element 64).

7. With regards to claim 2, the cover of Hassanein is fitted on top of the cart that secures the organ container and it is inherent in the teachings of Hassanein that the container is "separable" from the cover (col. 11 lines 45-47, Fig. 4 element 180). With regards to claim 6, Hassanein teaches that University of Wisconsin solution can be used as a cardioplegic preservation solution (col. 1 lines 51-53). Ror claim 7,

Hassanein teaches a pump (Fig. 1 element 38) that re-circulates the blood to the oxygenating membrane and the left atrium supply line (Fig. 1 element 54) is connected to the aortic cannula (col. 8 lines 55-56, Fig. 2 elements 54 &124). Also, the pulmonary artery line (Fig. 1 element 64) which returns the de-oxygenated blood back to the reservoir is connected to the arterial cannula (col. 8 lines53-54, Fig. 2 elements 64 & 122) and the aorta line (Fig. 1 element 58) is connected to the aortic cannula (col. 8 lines 54-55, Fig. 2 elements 58 & 120). The three cannulae are part of the cannula plate (Fig. 2 element 106) that is part of the cover assembly (col. 8 lines 9-11, Fig. 2 element 22). With regards to claim 9, Hassanein teaches a cart (Fig. 4 element 140) supports the gas bottle on the middle shelf and the organ container on the top shelf (col. 11 lines 32-33) and for claim 11, the cannula plate is part of the cover assembly (col. 7 lines 42-45, Fig. 3 elements 22 & 106) where for claim 12 the cannula plate includes a tongue-and-groove arrangement for securing (**sealing**) the plate to the cover assembly (col. 7 lines 51-55, Fig. 3 elements 106, 108 & 110).

8. For claim 14, Hassanein teaches that the gas source is a gas bottle (col. 5 lines 63-64, Fig. 4 element 179). For claim 15, Hassanein teaches a cannula plate that is used to secure various cannulas that attach to the organ (col. 8 lines 7-9) that feeds the oxygenated blood from the oxygenating membranes to the organ (Fig. 1 elements 38, 44, 48, 54) and for claim 16, the various lines (pulmonary artery line, aorta line, left atrium supply line) to be attached to a respective cannula (arterial, aortic and left atrial respectively) (col. 8 lines 53-56) and are secured to the organ by a surgical suture (co. 8 lines38-39).

9. For claim 19, Hassanein teaches a cover that is fitted on top of the perfusion system (col. 11 lines 46-48, Fig. 4 element 180) that provides additional protection to the system. Also, Hassanein teaches a organ container (col. 11 lines 20-21, Fig. 4 element 20) that allows for the return of any blood that escapes the organ (col. 4 lines 40-41) that includes a cover assembly that has a clamping ring which has two-halves, i.e. the ring opens in a horizontal motion, that are connected by a hinge (col. 7 lines 36-38, Fig. 3 element 22). Also, Hassanein includes an oxygen bottle with regulator for providing the right percentage of oxygen and carbon dioxide to the heart organ (col. 11 lines 32-33, Fig. 4 element 178) and is introduced to the blood perfusion via the oxygenating membrane. The blood perfusion is returned to the reservoir via a drain connector in the organ container (col. 4 lines 37-39, Fig. 1 elements 24-26,30) and the blood perfusion is returned to the reservoir by the pulmonary artery return line (col. 7 lines 9-10, Fig. 1 element 64).

10. With regards to claim 20, Hassanein teaches that the blood perfusion is oxygenated by the oxygenating membrane and is sent from the oxygenator to the organ container via a conduit (Fig. 1, Abstract). For claim 22, Hassanein teaches a cannula plate that is used to secure various cannulas that attach to the organ (col. 8 lines 7-9) that feeds the oxygenated blood from the oxygenating membranes to the organ (Fig. 1 elements 38, 44, 48, 54) and for claim 23, the various lines (pulmonary artery line, aorta line, left atrium supply line) to be attached to a respective cannula (arterial, aortic and left atrial respectively) (col. 8 lines 53-56) and are secured to the organ by a surgical suture (co. 8 lines38-39).

11. For claim 26, the cover of Hassanein is fitted on top of the cart that secures the organ container and it is inherent in the teachings of Hassanein that the container is "separable" from the cover (col. 11 lines 45-47, Fig. 4 element 180). With regards to claim 27, Hassanein also teaches that the organ container is a thick, yet soft flexible plastic in the form of a zipper bag (col. 4 lines 28-30). Therefore, Hassanein meets the limitations of claims 1, 2, 6, 7, 9, 11, 12, 14, 15, 16, 19, 20, 22, 23, 26 and 27.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 3-5, 10, 13, 17, 24 and 28-31 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (U.S. 6,100,082) in view of Gaugler et al. (U.S. 6,432,698).

15. With regards to claim 3, Hassanein teaches that the blood perfusion is oxygenated by the oxygenating membrane and is sent from the oxygenator to the organ container via a conduit (Fig. 1, Abstract). Furthermore, the blood perfusion enters the organ through the left atrium supply line (Fig. 1 element 54) which is connected to the aortic cannula that is part of the cannula plate (col. 8 lines 53-53, Fig. 3 elements 54 and 120). Hassanein does not mention that the gas source is connected directly to the cannula or that there is a second conduit leading into the chamber. For claim 4, Hassanein does teach a filter in between the oxygenating membrane (Fig. 1 element 46) and the aortic cannula, but this filter is for the blood perfusion and does not filter out microorganisms in the air stream. However, the filter of Hassanein is a leukocyte filter (col.5 lines 6-7) that does filter out contaminants that could adversely affect the preserved organ. With regards to claim 5, Hassanein does not mention a gas release mechanism at the end of the second conduit.

16. Gaugler teaches a disposable bioreactor for culturing microorganisms that provides for mixing and gas exchange within the culture medium by bubbling gas through the medium. Specifically, Gaugler discloses a gas bubbler with various types of diffusers that promote mixing of a culture within a bioreactor and aerates the culture contained within the chamber. Regarding claim 3, Gaugler discloses a tube that extends from the gas pump through an inlet and into the internal chamber of the

bioreactor (col. 5 lines 60-63, Fig. 6 elements 17 & 22). In regards to claim 4, Gaugler teaches a micro-filter (Fig. 6 element 24) in between the gas source (Fig. 6 element 26) and the chamber (col. 4 lines 63-64) and for claim 5, the air bubbles are directed to the bottom of the chamber where the tube is connected to a gas diffuser (col. 5 lines 63-65). It would have been obvious to one of ordinary skill in the art to employ the gas tube, filter and gas diffuser as suggested by Gaugler in order to provide mixing for a culture medium. The suggestion for doing so at the time would have been in order to provide gas exchange to the medium and provide mixing of the culture contained within (Abstract).

17. With regards to claim 10, Gaugler teaches an exhaust vent (col. 4 lines 64-66, Fig. 6 element 16b). One of ordinary skill in the art would find it obvious to modify the organ preservation container of Hassanein with the pressure vent of Gaugler in order to release excess pressure from the container.

18. With regards to claim 13, the tongue and groove structure of the cannula plate of Hassanein provides the same sealing function as a gasket, but does not mention the use of a gasket for sealing the cover assembly. Furthermore, the use of a gasket to provide hermetic sealing of a plate or lid is well known within the art. Therefore, it would have been obvious to one of ordinary skill in the art to employ a gasket to seal the top of the organ preservation chamber in order to maintain a hermetic environment for the organ.

19. With regards to claim 17, Hassanein teaches that the left atrium supply line is connected to the oxygenating membrane which is connected to a cannula on the

cannula support plate. Hassanein does not teach the gas directing means is directly connected to the container and that a second conduit leads into the container. Gaugler teaches that the air supply conduit (Fig. 6 element 22) enters the interior of the chamber of the bioreactor and thus, is in flow communication with the conduit from the air supply pump (Fig. 6 element 26). Therefore, it would have been obvious to one of ordinary skill in the art to employ the conduit as suggested by Gaugler within the teachings of Hassanein in order to deliver a gas supply to the organ container.

20. With regards to claim 24, Hassanein teaches that the left atrium supply line is connected to the oxygenating membrane which is connected to a cannula on the cannula support plate. Hassanein does not teach the gas directing means is directly connected to the container and that a second conduit leads into the container. Gaugler teaches that the air supply conduit (Fig. 6 element 22) enters the interior of the chamber of the bioreactor and thus, is in flow communication with the conduit from the air supply pump (Fig. 6 element 26). Therefore, it would have been obvious to one of ordinary skill in the art to employ the conduit as suggested by Gaugler within the teachings of Hassanein in order to deliver a gas supply to the organ container.

21. For claim 28, Hassanein teaches that the preservation chamber is a soft flexible plastic in the form of a zipper bag (**film [...] having a main opening**) (col. 4 lines 28-30) with an opening for containing the organ. Also, Hassanein teaches a cover that is fitted on top (**connector part surrounding [...] opening**) of the perfusion system (col. 11 lines 46-48, Fig. 4 element 180) that provides additional protection to the system. The cover includes a cannula plate that allows for the attachment of cannula for flow of

perfusate to the organ (**three hose barbs**) (Fig. 3 elements 106, 120, 122 & 124). Also, Hassanein teaches a organ container (col. 11 lines 20-21, Fig. 4 element 20) that allows for the return of any blood that escapes the organ (col. 4 lines 40-41) that includes a cover assembly that has a clamping ring which has two-halves, i.e. the ring opens in a horizontal motion, that are connected by a hinge (col. 7 lines 36-38, Fig. 3 element 22). Also, Hassanein includes an oxygen bottle with regulator for providing the right percentage of oxygen and carbon dioxide to the heart organ (col. 11 lines 32-33, Fig. 4 element 178) and is introduced to the blood perfusion via the oxygenating membrane. The blood perfusion is returned to the reservoir via a drain connector in the organ container (col. 4 lines 37-39, Fig. 1 elements 24-26,30) and the blood perfusion is returned to the reservoir by the pulmonary artery return line (col. 7 lines 9-10, Fig. 1 element 64). With regards to medium recirculation, Hassanein teaches that the blood perfusion is oxygenated by the oxygenating membrane and is sent from the oxygenator to the organ container via a conduit (Fig. 1, Abstract). Furthermore, the blood perfusion enters the organ through the left atrium supply line (Fig. 1 element 54) which is connected to the aortic cannula that is part of the cannula plate (col. 8 lines 53-53, Fig. 3 elements 54 and 120). Hassanein does not mention that the gas source is connected directly to the cannula or that there is a second conduit leading into the chamber. Also, while Hassanein teaches a main opening with a cannula plate that has three openings, Hassanein does not teach that the film has a main opening plus three flow openings.

22. With regards to the three flow openings of claim 28, Gaugler discloses three ports or **flow openings** which include the gas inlet (Fig. 6 element 16a), an outlet port

(Fig. 5 element 16b) and an inoculation port (Fig. 6 element 16c). These ports allow for the introduction of gas to the bioreactor (Fig. 6 element 16a) and for the exhaust of gas due to the reaction within the bioreactor (col. 3 lines 1-3). Also, Gaugler teaches an inoculation port that introduces inoculum from another chamber (col. 3 lines 15-18). Therefore, it would have been obvious to one of ordinary skill in the art to employ the ports as suggested by Gaugler within the teachings of Hassanein in order to allow the introduction of gas or nutrient to the organ container.

23. Regarding claim 28, Gaugler discloses a tube that extends from the gas pump through an inlet and into the internal chamber of the bioreactor (col. 5 lines 60-63, Fig. 6 elements 17 & 22). It would have been obvious to one of ordinary skill in the art to employ the gas tube, filter and gas diffuser as suggested by Gaugler in order to provide mixing for a culture medium. The suggestion for doing so at the time would have been in order to provide gas exchange to the medium and provide mixing of the culture contained within (Abstract).

24.

25. For claim 29, Gaugler also includes a culture medium within the disposable bioreactor (Abstract). Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to employ the surrounding culture medium as suggested by Gaugler within the teachings of Hassanein in order to preserve the organ. The suggestion for doing so at the time would have been in order to provide an ideal storage condition for the organ.

26. For claim 30, Hassanein teaches a cover that is fitted on top of the perfusion system (col. 11 lines 46-48, Fig. 4 element 180) that provides additional protection to the system. Also, Hassanein teaches a organ container (col. 11 lines 20-21, Fig. 4 element 20) that allows for the return of any blood that escapes the organ (col. 4 lines 40-41) that includes a cover assembly that has a clamping ring which has two-halves, i.e. the ring opens in a horizontal motion, that are connected by a hinge (col. 7 lines 36-38, Fig. 3 element 22). Also, Hassanein includes an oxygen bottle with regulator for providing the right percentage of oxygen and carbon dioxide to the heart organ (col. 11 lines 32-33, Fig. 4 element 178) and is introduced to the blood perfusion via the oxygenating membrane. The blood perfusion is returned to the reservoir via a drain connector in the organ container (col. 4 lines 37-39, Fig. 1 elements 24-26,30) and the blood perfusion is returned to the reservoir by the pulmonary artery return line (col. 7 lines 9-10, Fig. 1 element 64). Hassanein also teaches that the organ container is a thick, yet soft flexible plastic in the form of a zipper bag (col. 4 lines 28-30). With regards to claim 28, Hassanein teaches that the blood perfusion is oxygenated by the oxygenating membrane and is sent from the oxygenator to the organ container via a conduit (Fig. 1, Abstract). Furthermore, the blood perfusion enters the organ through the left atrium supply line (Fig. 1 element 54) which is connected to the aortic cannula that is part of the cannula plate (col. 8 lines 53-53, Fig. 3 elements 54 and 120). Hassanein does not mention that the gas source is connected directly to the cannula or that there is a second conduit leading into the chamber.

27. Regarding claim 30, Gaugler discloses a tube that extends from the gas pump through an inlet and into the internal chamber of the bioreactor (col. 5 lines 60-63, Fig. 6 elements 17 & 22). It would have been obvious to one of ordinary skill in the art to employ the gas tube, filter and gas diffuser as suggested by Gaugler in order to provide mixing for a culture medium. The suggestion for doing so at the time would have been in order to provide gas exchange to the medium and provide mixing of the culture contained within (Abstract).

28. With regards to claim 31, Hassanein teaches providing a preservation chamber for containing the organ and a perfusion circuit associated with the preservation chamber (col. 3 lines 10-11). Also, Hassanein teaches that the step where the perfusion circuit has a first line delivering fluid to the organ and a second line for carrying the fluid away from the organ (col. 3 lines 13-15) and placing the preservation chamber onto the cart (col. 11 lines 19-21) where a clear plastic cover can be fitted on top of the cart (col. 11 lines 46-47). Hassanein also teaches the step of attaching a cannula to the arteries of the organ (col. 8 lines 31-33) and connecting the cannula plate (Fig. 3 element 106) to the cover assembly (col. 7 lines 41-43). The preserving solution of Hassanein is circulated through the perfusion circuit and sent to the heart in the organ container (col. 4 lines 11-13) and using the venous lines for carrying the depleted perfusion fluid away from the organ (col. 4 lines 15-16). Also, the step of removing the cannula plate to expose the interior of the chamber while not explicitly stated is inherent in the teachings of Hassanein. Furthermore, Hassanein teaches the step of having an

oxygen bottle on the same cart as the preservation chamber and membrane oxygenator (col. 11 lines 32-35).

29. Hassanein does not teach attaching a gas release device to the second pipe, but does teach attaching an oxygen bottle to the oxygenating membrane in order to provide the perfusion fluid with the preferred mixture of oxygen and carbon dioxide (col. 4 lines 57-58 & 62-64). Gaugler teaches the step of connecting the gas pump to the tube that allows air to be sent into the interior of the bioreactor (col. 5 lines 61-63). It would have been obvious to one of ordinary skill in the art to employ the gas tube as suggested by Gaugler in order to provide mixing for a culture medium. The suggestion for doing so at the time would have been in order to provide gas exchange to the medium and provide mixing of the culture contained within (Abstract).

30. Claim 8, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (U.S. 6,100,082) in view of Singh (U.S. 6,544,788).

31. Hassanein is silent regarding the limitation of claim 8. Regarding claim 18, Hassanein teaches that the pump is connected to the reservoir via a conduit (Fig. 1 element 32) which then pumps the blood perfusion to the oxygenating memebrane (Fig. 1 element 38) and to the organ container (Fig. 1 element 20). Also, the blood perfusate of Hassanein leaves the organ via a venous line (col. 4 lines 16-17, Fig. 1 element 18) to a reservoir (Fig. 1 element 30). From the reservoir, the blood perfusion fluid proceeds to a pump that sends the fluid to the oxygenating membrane. However, Hassanein does not disclose that the uptake of the perfusate is through a conduit within the container.

32. Singh teaches a disposable wave bioreactor that is used for the culturing of cells for use in cell and gene therapy applications. Singh teaches a tube contained within the body of the bioreactor with a filter attachment that moves across the top of the culture medium due to the pivot action of the bioreactor. This reduces the tendency of the bioreactor to become clogged with the cell harvest during normal operation. Furthermore, the interior tube provides flexibility in the way the filter traverses the interior of the bioreactor such that more surface area is potentially covered. With regards to claim 8, Singh discloses a tube with a filter for the uptake of cell product from a bioreactor (Abstract). While Singh does not specify that the intake has to be below the surface of the culture medium, it is within the skills of one of ordinary skill in the art to place the intake valve in order to minimize the potential for air entrapment within the feed lines. One of ordinary skill in the art would find this obvious in order to prevent air bubbles from being captured by the organ before transplantation. With regards to claim 18, Singh teaches a tube within the internal chamber of the bioreactor (col. 3 lines 18-20, Fig. 2 element 22). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to employ the tube as suggested by Singh within the teachings of Hassanein in order to pull culture medium from the container.

33. With regards to claim 21, Hassanein teaches a pump (Fig. 1 element 38) that re-circulates the blood to the oxygenating membrane and the left atrium supply line (Fig. 1 element 54) is connected to the aortic cannula (col. 8 lines 55-56, Fig. 2 elements 54 &124). Also, the pulmonary artery line (Fig. 1 element 64) which returns the de-oxygenated blood back to the reservoir is connected to the arterial cannula (col. 8

lines53-54, Fig. 2 elements 64 & 122) and the aorta line (Fig. 1 element 58) is connected to the aortic cannula (col. 8 lines 54-55, Fig. 2 elements 58 & 120). The three cannulae are part of the cannula plate (Fig. 2 element 106) that is part of the cover assembly (col. 8 lines 9-11, Fig. 2 element 22). Hassanein does not teach a flexible tube within the bioreactor for the take up of culture medium.

34. Singh teaches a disposable wave bioreactor that is used for the culturing of cells for use in cell and gene therapy applications. Singh teaches a tube contained within the body of the bioreactor with a filter attachment that moves across the top of the culture medium due to the pivot action of the bioreactor. This reduces the tendency of the bioreactor to become clogged with the cell harvest during normal operation. Furthermore, the interior tube provides flexibility in the way the filter traverses the interior of the bioreactor such that more surface area is potentially covered. With regards to claim 21, Singh teaches a tube within the internal chamber of the bioreactor (col. 3 lines 18-20, Fig. 2 element 22). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to employ the tube as suggested by Singh within the teachings of Hassanein in order to pull culture medium from the container.

35. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassanein (U.S. 6,100,082) in view of Gaugler et al. (U.S. 6,432,698) and in further view of Singh (U.S. 6,544,788).

36. Regarding claim 25, Hassanein and Gaugler teach that the pump is connected to the reservoir via a conduit (Fig. 1 element 32) which then pumps the blood perfusion to

the oxygenating memebrane (Fig. 1 element 38) and to the organ container (Fig. 1 element 20). Also, the blood perfusate of Hassanein leaves the organ via a venous line (col. 4 lines 16-17, Fig. 1 element 18) to a reservoir (Fig. 1 element 30). From the reservoir, the blood perfusion fluid proceeds to a pump that sends the fluid to the oxygenating membrane. However, Hassanein and Gaugler do not disclose that the uptake of the perfusate is through a conduit within the container and Gaugler does not disclose an intake conduit for the perfusate.

37. Singh teaches a disposable wave bioreactor that is used for the culturing of cells for use in cell and gene therapy applications. Singh teaches a tube contained within the body of the bioreactor with a filter attachment that moves across the top of the culture medium due to the pivot action of the bioreactor. This reduces the tendency of the bioreactor to become clogged with the cell harvest during normal operation. Furthermore, the interior tube provides flexibility in the way the filter traverses the interior of the bioreactor such that more surface area is potentially covered. With regards to claim 25, Singh teaches a tube within the internal chamber of the bioreactor (col. 3 lines 18-20, Fig. 2 element 22). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to employ the tube as suggested by Singh within the teachings of Hassanein and Gaugler in order to pull culture medium from the container.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kern (U.S. 5,362,642) teaches a containment system that includes a flexible bag within a storage bag that has a introduction plate that has two conduits for the removal and introduction of air. Also, Gardetto et al. (U.S. 5,965,433) teaches a portable perfusion system where the organ is within a container and the system does not require any electrical power to operate. The art taught by Bacehowski et al. (U.S. 4,968,624) includes a flexible bag for holding culture medium with two hose barbs with tubes that allow the contained fluid to flow out of the bag. A solution for preserving organs is taught by Belzer et al. (U.S. 4,879,283) that is known in the art as University of Wisconsin solution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL L. HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mikhail Kornnakov can be reached on (571) 272-1303. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLH
/Michael Kornakov/
Supervisory Patent Examiner, Art Unit 4151